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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,967	12/02/2003	Marcus Ballinger	2004345-0021 (SU-2600 US)	4388

7590 06/07/2005

ATTN: Nadege M. Lagneau, Ph.D.
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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,967

Applicant(s)

BALLINGER, MARCUS

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

RD

DETAILED ACTION

Claims 1-20 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a BACE protease polypeptide, classified in class 435, subclass 226.
- II. Claims 18-20, drawn to a polynucleotide encoding a BACE protease polypeptide, vector, and host cell comprising the polynucleotide, classified in class 536, subclass 23.2.

For each of Inventions I-II above, restriction to one of the following is also required under 35 USC 121 and 327. Therefore, election is required of one of Inventions I-II and one of Inventions (A)-(H), one of Inventions (I)-(Q), and one of Inventions (R)-(S).

Elect an autoproteolysis site from:

- (A.) A specific sequence that is a combination of X1-X2-X3-X4-X5, wherein
 - X1 is Glu or Gln,
 - X2 is Leu, Ile, or Val,
 - X3 is Asn, Asp, or Met,
 - X4 is Leu or Phe, and
 - X5 is Glu, Met, Gln, Ser, Ala, or Asp
- (B.) SEQ ID NO: 56
- (C.) SEQ ID NO: 57
- (D.) SEQ ID NO: 58

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(E.) SEQ ID NO: 59

(F.) SEQ ID NO: 60

(G.) SEQ ID NO: 61

(H.) SEQ ID NO: 62

Elect a protease domain from:

(I.) Comprises at least 20 contiguous residues from 74-446 of SEQ ID NO: 1

(J.) SEQ ID NO: 52

(K.) SEQ ID NO: 53

(L.) SEQ ID NO: 54

(M.) SEQ ID NO: 55

(N.) Comprises at least 60 contiguous residues from 74-446 of SEQ ID NO: 1

(O.) Comprises at least 120 contiguous residues from 74-446 of SEQ ID NO: 1

(P.) Comprises at least 180 contiguous residues from 74-446 of SEQ ID NO: 1

(Q.) Comprises 74-446 of SEQ ID NO: 1

Elect a prodomain from:

(R.) Residues 22-41 of SEQ ID NO: 1

(S.) Residues 22-45 of SEQ ID NO: 1

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different

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process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The polynucleotide of Invention II is related to the polypeptide of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the polypeptide in host cells. Although the DNA molecule and polypeptide are related, since the DNA encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the polypeptide, such as in a nucleic acid hybridization assay.

A search for more than one of Inventions I-II would be a burden on the Office for the following reasons.

The search of Invention II would not encompass a search for Invention I, which would include searching the prior art for teachings of the purified polypeptide. Conversely, a search for Invention I, class 435, subclass 226, would not encompass a search for Invention II, which would also include searching class 435, subclasses 69.1, 252.3, and 320.1 as well as class 536, subclass 23.2. Thus, a search of either Invention I or II would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different

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classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.



AV/652